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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,317	12/17/2003	Timothy A. Becker	65306-0092	8901

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RADER, FISHMAN & GRAUER PLLC  
39533 WOODWARD AVENUE  
SUITE 140  
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/738,317

Applicant(s)

BECKER ET AL.

Examiner

James W. Rogers, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,5-17 and 21-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-17,21-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment to the claims filed 08/21/2006 has been entered.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,17,23,27,34,36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 1,17,23 and 27 are presently amended to include the new limitation that the injection of purified alginate liquid and injection of the calcium chloride solution can be at variable rates, either within an injection stage or across injection stages. While the specification has support for a variable injection or an injection in stages the examiner could find no support for the above specific limitation. To expedite the examining process since the phrase "can be" fails to further limit the claims the examiner will ignore the limitation when applying art. Claims 34 and 36 recite the limitation that the alginate liquid is of a MW less than 250,000, while the specification has support for an alginate with a MW range: 65,000 g/mol to 200,000 g/mol it does not have support for the broader limitation above in which the alginate can be any MW below 250,000 as claimed. To expedite the examining

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process the examiner searched for the MW range that was supported in the specification that is a MW range: 65,000 g/mol to 200,000 g/mol for the alginate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 1,17,23 and 27, the phrase "can be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,5-17,21-22,35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kipke et al. (US 2001/0031978 A1).

Kipke teaches a method for forming an endovascular occlusion comprised of controlling the injection rate and pressure of a purified alginate and calcium chloride solution. See abstract, [0003], [0013], [0015], [0035],[0071] and claims. Regarding claims 35 and 37 Kipke discloses in figure 7a that the concentration of the solution can be about or a little lower than 25 cp from the graph, therefore the limitation is met. Kipke also teaches several injection techniques including staged injections. Regarding claims 15-16 Kipke teaches that the alginate solution may also contain a radioactive contrast agent. See [0012].

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,5-17,21-22,34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 2001/0031978 A1).

Regarding claims 33-34 and 36, Kipke while disclosing the use of alginates with different guluronic acid and mannuronic acid content is silent on the exact MW of the alginates, although the examiner concludes that the Kipke application obviously incorporates the same alginates with the same MW because both applications bought the alginates from the same source (Provova) and apparently used the same commercially available alginates, the burden is shifted to the applicants to show that the molecular weight range claimed within their currently claimed invention is not

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encompassed within the Kipke application. Regarding the limitations on the injection rates of the calcium and alginate solutions in claims 1 and 5-14 it would have been obvious at the time of the invention to vary the injection rates of the alginate and calcium chloride solution because Kipke discloses that the calcium alginate is optimized for forming an endovascular occlusion by controlling the injection rate, pressure and viscosity of the purified alginate solution and calcium chloride solution. Therefore it would have been obvious through routine experimentation to vary the injection rate of both solutions in order to optimize the formation of an endovascular occlusion. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1,5-17,21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 2001/0031978 A1) in view of Reeves (US 5,222,970) in view of Ji et al. (US 5,894,022).

Kipke is disclosed above. Kipke does not disclose injecting the calcium chloride solution into a balloon nor does the application disclose the use of a coil in conjunction with the purified alginate and calcium chloride.

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Reeves is used only to show that using a catheter to inflate a balloon with a polymer for vascular occlusion was already known at the time of the invention. See abstract and col 6 lin 40-47.

Ji is used only to show that using a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil was already known at the time of the invention. See col 6 lin 23-38.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Kipke discloses the same polymeric alginate composition for vascular occlusion as applicant while Reeves and Ji showed the use of a catheter to inflate a balloon with a polymer for vascular occlusion and use of a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil were already known at the time of the invention. The motivation to combine the above documents would be a method for vascular occlusion by controlling the injection of a purified alginate and calcium chloride solution that could also be used in conjunction with a coil or the calcium alginate solution could be used to inflate a balloon for vascular occlusion. The benefit of the above method would be an administration that enables control of the occlusion agent to meet and polymerize at the target site. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

### **Conclusion**

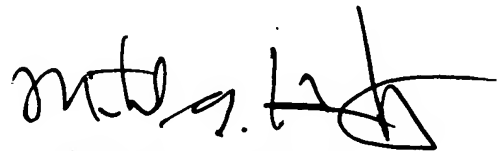
No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

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whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'm. g. hartley', with a stylized flourish at the end.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER